

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0485V

UNPUBLISHED

KIMBERLEE WINKLE,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 3, 2021

Special Processing Unit (SPU);
Findings of Fact; Onset; Influenza
(Flu) Vaccine; Ruling on Entitlement;
Table Injury; Shoulder Injury Related
to Vaccine Administration (SIRVA)

Leah Finfer, Muller Brazil LLP, Dresher, PA, for Petitioner.

Andrew Henning,¹ U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT²

On March 27, 2020, Kimberlee Winkle filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*³ (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”) caused by the influenza (“flu”) vaccine she received on November 11, 2017. Petition at 1, ¶¶ 2, 15. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Until December 6, 2020, Lisa Watts was Respondent’s counsel in this case. ECF No. 18 (Notice of Appearance from Andrew Henning).

² Because this unpublished Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

³ National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the onset of Petitioner's SIRVA occurred within 48 hours of vaccination. Specifically, Petitioner suffered pain immediately upon vaccination. Additionally, I find that Petitioner has satisfied the requirements of a Table SIRVA. Petitioner is entitled to compensation under the Vaccine Act.

I. Relevant Procedural History

Along with the Petition, Ms. Winkle filed her affidavit, an affidavit from her sister, and some of the medical records required by the Vaccine Act. Exhibits 1-7, ECF No. 1. On May 19, 2020, she filed a supporting affidavit from her friend, Ann Muir Moomaw, whom she visited shortly after receiving the flu vaccine. Exhibit 8, ECF No. 11.

Following the initial status conference, held on July 17, 2020, Petitioner filed an amended Petition, correcting one minor mistake – an incorrect date, and her remaining medical records. Amended Petition, ECF No. 14; Exhibit 9, ECF No. 15. While Respondent's counsel agreed that all required medical records had been filed, she speculated that "the onset of [P]etitioner's left shoulder pain is likely to be an issue in this case." Status Report, Nov. 9, 2020, at 2, ECF No. 17. Respondent's counsel based her observation on the fact that Petitioner delayed seeking treatment until five months after vaccination, on April 6, 2018, and an entry from a visit one month later, on May 15, 2018 when she was observed to have normal range of motion ("ROM"). *Id.*

Petitioner was instructed to file any additional evidence regarding the onset of her SIRVA symptoms. Non-pdf Scheduling Order, issued Dec. 1, 2020. On February 17, 2021, Petitioner filed a status report communicating her belief "that all relevant records and evidence, including her own affidavit and two witness affidavits, have been filed at this time." ECF No. 20.

On April 5, 2021, I issued a ruling on entitlement, since withdrawn, finding that the onset of Petitioner's pain occurred within 48 hours of vaccination and that Petitioner's injury met all requirements for a Table SIRVA. See 42 C.F.R. § 100.3(a) XIV.B. (2017) (Table SIRVA following receipt of the influenza vaccine); 42 C.F.R. § 100.3(c)(10) (additional criteria for SIRVA listed in the Qualifications and aids to interpretations ("QAI")). On April 26, 2021, Respondent filed a timely motion for reconsideration, which I granted. ECF Nos. 23-24. As the basis for his request, Respondent maintained that I first should allow Respondent to state his tentative position regarding the merits of Petitioner's case following the review by medical personnel at Health & Human Services ("HHS"), a task which has been delayed due to the large number of vaccine cases filed since 2016. Respondent's Motion for Reconsideration at 4-5, 8-11. Respondent added that HHS

medical personnel may identify additional medical records which are needed in the case. *Id.* at 11. When granting Respondent's motion, I ordered Respondent to file a status report or Rule 4(c) Report indicating whether he believes Petitioner's injury meets the definition for a Table SIRVA, listing any criteria he believes has not been satisfied, and providing the basis for this belief. ECF No. 24.

On May 26, 2021, Respondent filed a status report indicating that he wished to engage in settlement discussions with Petitioner. ECF No. 26. During email correspondence with the OSM staff attorney assisting me on this SPU case, Respondent's counsel confirmed that Respondent's objection to compensation is based solely on his belief that the onset of Petitioner's pain did not occur within 48 hours of vaccination. See Informal Remark, dated May 27, 2021. He further confirmed that Respondent did not wish to supplement the record with any additional briefing. Petitioner's counsel indicated Petitioner did not wish to file a response as was allowed for in my earlier order. *Id.*; see ECF No. 24 (order granting Respondent's motion for reconsideration).

II. Finding of Fact Regarding Onset

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and QAI for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B.; 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

A. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-

1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that “written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that “medical records may be incomplete or inaccurate.” *Camery v. Sec’y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

B. Analysis

I make the finding regarding onset after a complete review of the record to include all medical records, affidavits, and additional evidence. Specifically, I base the findings on the following evidence:

- Prior to receiving the flu vaccine, Petitioner was seen for her annual physical on January 31, 2017. There is no evidence of any left shoulder pain in this record or any of the prior medical records. Exhibit 2 at 17-19.
- Petitioner received the flu vaccine alleged as causal in her left deltoid on November 11, 2017. Exhibit 1 at 4, 7.
- Petitioner did not seek treatment for her left shoulder pain until seen by her primary care provider (“PCP”) for her next annual physical on April 6, 2018 – nearly five months post-vaccination. Exhibit 2 at 14-16. At this visit, she reported that the soreness she experienced when she had her flu vaccine “ha[d] never resolved” and developed into pain with ROM. *Id.* at 14. Upon examination, her PCP observed “pain with ROM at or near [the] site of vaccination.” *Id.* at 15. Petitioner was referred to an orthopedist. *Id.* at 16.
- At her first orthopedic visit, on April 18, 2018, Petitioner reported “[l]eft arm pain at injection site in left deltoid area” which has never gotten better, only worse. Exhibit 3 at 39. Describing her pain as aching and throbbing with loss of ROM and stiffness, Petitioner indicated the onset of her injury was November 11, 2017. *Id.* The orthopedist administered a cortisone injection and prescribed physical therapy (“PT”). *Id.* at 43.
- At her initial PT evaluation on May 2, 2018, Petitioner reported “onset of left shoulder pain and stiffness [on] 11/11/2017 after receiving a flu shot.” Exhibit 4 at 118. She again described “continued increasing soreness following her flue [sic] shot, which never went away.” *Id.* Regarding specific tasks, she reported difficulty taking off her jacket, blowing her hair, reaching behind her back, and reaching for the phone at work. *Id.* Upon examination, Petitioner exhibited limited continued ROM. *Id.* at 119-20.
- On May 15, 2018, Petitioner was seen by her PCP for an issue with her thyroid and follow-up labs. Exhibit 2 at 11. In the medical record from this visit, it is noted that Petitioner was recently diagnosed with adhesive capsulitis, seen by an orthopedist, and was currently undergoing PT. *Id.*

Under the examination section (musculoskeletal), normal ROM is listed. Petitioner was diagnosed with hypothyroidism and prescribed medication. *Id.* at 12.

- In the medical history from a January 31, 2019 visit to the orthopedist, it was again noted that Petitioner's left shoulder pain "started after she got her flu shot about 15 months ago." Exhibit 3 at 25. Her diagnosis was "SIRVA. Shoulder injury after vaccine administration." *Id.* at 27. It was also noted that she had "[m]inimal improvement of ROM after PT." *Id.*
- When Petitioner returned to PT in February 2019, she again reported receiving "a flu shot in November 2017 . . . [and] had lateral deltoid pain ever since" and listed the onset of her pain as 11/11/2017. Exhibit 4 at 82. She exhibited left shoulder decreased ROM for both passive and active movements. *Id.* at 84-85. Her PT goals included increased motion and decreased pain. *Id.* at 82.
- Petitioner returned to the orthopedist in late March and April, 2019. Exhibit 3 at 12-23. On March 28, 2019, she reported improvement, mild soreness, and pain at a level of two out of ten. *Id.* at 19. By May 29, 2019, she had reached a plateau with continued pain and decreased ROM. *Id.* at 12.
- At an orthopedic appointment on October 8, 2019, almost two years after vaccination, Petitioner described her onset as gradual and indicated that her problem "began 1-2 years ago." Exhibit 3 at 5.
- At her annual physical on November 6, 2019, it was noted that Petitioner "[h]ad frozen shoulder from last flu shot - refuses all shots." Exhibit 2 at 4.
- Petitioner submitted affidavits from her sister and friend which support the facts and circumstances she alleges. Exhibits 7-8.

It is common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own. Thus, while the five-month delay in this case is longer than most, it is not unreasonable, given Petitioner's description of a gradually increasing pain level. Additionally, Petitioner did not seek treatment for any other medical condition or illness during this five-month period. Such intervening treatment evidence can in many cases either corroborate a petitioner's claim or undermine it – but it is totally absent here.

In multiple post-vaccination medical records, Petitioner consistently reported left shoulder pain, which never ceased, immediately upon vaccination. Without fail, she attributed her injury to the flu vaccine she received on November 11, 2017. On multiple occasions she identified the date of onset as November 11, 2017. While these entries were based upon information provided by Petitioner, they still should be afforded greater weight than more current representations, as they were uttered contemporaneously with Petitioner's injury for the purposes of obtaining medical care.

The Federal Circuit has stated that “[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions.” *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when the information is provided by Petitioner.

In addition to Petitioner's delay in treatment, Respondent's counsel emphasized two entries which she believed undercut Petitioner's claim of immediate onset. First, she noted that normal ROM was observed during a PCP appointment in May 2018 - one month *after* Petitioner first complained of her SIRVA. Status Report, filed Nov. 9, 2017, at 2, ECF No. 17 (comparing Exhibit 2 at 15⁴ (4/6/18 record) with *id.* at 11 (5/15/18 record)). However, this later visit was for a thyroid issue and follow-up for labs. *Id.* Thus, it is unlikely a ROM examination was performed, or would have been contemplated at a visit for a different medical concern. Additionally, by this time Petitioner had seen the orthopedist, per her PCP's referral, and attended two PT sessions. Exhibit 3 at 39-45; Exhibit 4 at 113-21. This treatment is noted in the PCP medical record from the May 15, 2018 visit. Exhibit 2 at 11. Limited ROM was observed by both the orthopedist and physical therapist. Exhibit 3 at 41; Exhibit 4 at 119-20.

Respondent's counsel also stressed the onset description, “1-2 years ago,” Petitioner provided in late 2019. Status Report at 2 n.1; see Exhibit 3 at 5 (record from October 8, 2019 orthopedic visit). This general description, provided two years after vaccination, does not negate the multiple other entries, created closer in time to her injury, when Petitioner provided the exact date of vaccination for onset or described her pain and soreness as occurring immediately and never ceasing.

Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain occurred within 48 hours of vaccination. Specifically, I find the onset of petitioner's pain immediately upon vaccination.

⁴ Respondent's counsel mistakenly referred to page 12, but it is clear this was a simple mistake.

III. Requirements for Table SIRVA

Because I have determined the onset of her left shoulder pain occurred immediately upon vaccination, Petitioner has met the timing required for a Table SIRVA and has fulfilled the second of the four QAI Table criteria. See 42 C.F.R. § 100.3(a)(XIV) (Table entry for SIRVA following influenza vaccine); 42 C.F.R. § 100.3(c)(10)(ii) (second QAI requirement). To establish that she suffered a Table SIRVA, Petitioner must satisfy the additional three QAI requirements. 42 C.F.R. § 100.3(c)(10)(i) (iii-iv).

The record in this case contains no indication that Petitioner suffered prior left shoulder issues. See 42 C.F.R. § 100.3(c)(10)(i). Nor is there evidence of any other condition or abnormality that would explain the left shoulder pain she experienced. See 42 C.F.R. § 100.3(c)(10)(iv).

Petitioner consistently characterized her left shoulder pain as soreness, aching, and throbbing in her left shoulder. Exhibits 2 at 14; 3 at 25, 39; 4 at 82, 118. Regarding its location, she described her pain as “in the deltoid muscle . . . right at the site” (Exhibit 3 at 25) and “located on the left upper arm” (*id.* at 39). At least one of her treating physicians observed “[t]enderness of the anterior deltoid, biceps, infraspinatus, middle deltoid, supraspinatus, teres minor and triceps.” Exhibit 4 at 119. Likewise, Petitioner exhibited limited ROM in only her left shoulder throughout 2018 and 2019. Exhibits 2 at 15; 3 at 27; 4 at 84-85, 119-20. Thus, Petitioner has satisfied all QAI criteria for a Table SIRVA.

IV. Additional Requirements for Entitlement

Because Petitioner has satisfied the requirements of a Table SIRVA, she need not prove causation. Section 11(c)(1)(C). However, she must satisfy the other requirements of Section 11(c) regarding the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

The vaccine record shows Petitioner received the flu vaccine in her left deltoid at a Rite Aid Pharmacy in California. Exhibit 1 at 4, 6-7; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i) (requiring administration within the United States or its territories). Additionally, there is no evidence that Petitioner has collected a civil award for his injury. See Section 11(c)(1)(E) (lack of prior civil award).

Finally, the medical records show that more than six months after vaccination, Petitioner continued to suffer the residual effects of her SIRVA. See Section 11(c)(1)(D)(i)

(statutory six-month requirement). At her May 16, 2018 PT session, Petitioner reported pain at a level of five out of ten and tenderness was observed. Exhibit 4 at 111-12. Thereafter, Petitioner attended approximately 12 additional PT sessions through July 2018 and continued to pursue treatment for her SIRVA as late as October 2019. Exhibits 3 at 5; 4 at 87-110. Thus, Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

V. Conclusion

Based on the entire record in this case, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation in this case.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master